Rev. 12/19/2006

Article 15. Data Cost-Sharing Sections 6310-6314

6310. Dispute Resolution Proceedings.

If agreement cannot be reached about the terms and amount of payment required pursuant to Food and Agricultural Code section 12811.5, at any time more than 90 days after the issuance of an irrevocable offer to pay, either the applicant, source, or data owner may initiate or with the consent of all parties, join a binding dispute resolution proceeding under the rules prescribed under Title 29 Code of Federal Regulations, Part 1440, or its successor provision, if any, or other rules to which the applicant and data owner may agree.

- (a) To the extent feasible, and upon mutual consent of the parties, the proceeding may be consolidated with any dispute resolution process taking place between the same parties and being conducted pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. Sec 136a et. seq.)
- (b) In determining the amount due under this section, the decisionmaker(s) of a dispute resolution proceeding shall consider, among other factors, that the data owner's exclusive right to sell the pesticide resulted in the data owner recovering all or part of the cost of generating the data.
- (c) The finding of the decisionmaker(s) in a dispute resolution proceeding shall be final and conclusive, and no official or court shall have power or jurisdiction to review that finding and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the dispute resolution proceeding or the decisionmaker(s) where there is a verified complaint with supporting affidavits attesting to specific instances of fraud, misrepresentation, or misconduct.
- (d) The parties to the dispute resolution proceeding shall share equally in the payment of fees and expenses of the dispute resolution process, except that each party shall bear its legal fees and its expenses.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.

Reference: Section 12811.5, Food and Agricultural Code.

6312. Noncompliance Notification.

Pursuant to Food and Agricultural Code section 12811.5(g), any notification to the Director of an applicant's failure to comply with its obligation under Food and Agricultural Code section 12811.5(a-d) shall be in writing and shall include, organized by the subsection and subparagraph below to which it is responsive:

- (a) <u>Identification of the applicant and the product registration challenged, including:</u>
 - (1) Applicant name and address;
- (2) Brand name and U.S. Environmental Protection Agency Registration Number of the product;
 - (3) Date of the Department's registration of the product; and
- (4) Identification of each current and/or past Department data requirement for which you claim the applicant failed to submit a study or otherwise satisfy, and for which the applicant failed to make your company an offer to pay.
- (b) With respect to the data for which the data owner claims the applicant failed to make an offer to pay.

6312. Noncompliance Notification., continued

- (b) (1) Identification of the Department's exact data requirement to obtain, amend, or maintain the data owner's product that the data was submitted to satisfy;
- (2) Identification of each study (including DPR document number and study record number) submitted and the corresponding data requirement it satisfied; and
- (3) The date each study was submitted to the Department and, if applicable, to the U.S. Environmental Protection Agency (including the Master Record Identification Number MRID).
- (c) A statement setting forth the specific provisions of noncompliance claimed indicating how the data owner's data meet the criteria set forth in Food and Agricultural Code section 12811.5(a) or (b) that make it subject to cost-sharing, providing any documentation currently known to the data owner in support of that contention.
- (d) Proof that, prior to making the notification to the Director pursuant to Food and Agricultural Code section 12811.5(g), the data owner has informed the applicant of its claim, provided the applicant with the information required in (a), (b), and (c), and allowed the applicant an opportunity of at least ten days to promptly make an offer to pay for the data that serves as a basis of the data owner's claim. This proof shall include copies of all correspondence between the data owner and the applicant related to this issue.
- (e) Proof that at the same time the data owner filed its notification to the Director of the applicant's failure to meet its obligation under Food and Agricultural Code section 12811.5(a-d), the data owner sent a copy of the notification and all accompanying data and information by certified mail to the applicant.
- (f) With respect to a claim that the applicant has failed to participate in a proceeding for reaching an agreement on compensation, failed to comply with an agreement related to compensation, or failed to pay an award resulting from a proceeding to determine compensation, proof of such failure including, but not limited to, all correspondence between the parties on the issue and a copy of the award resulting from a proceeding on compensation, if any.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.

Reference: Section 12811.5, Food and Agricultural Code.

6314. Determination.

All parties shall have 30 days from receipt of the copy of the notification to the Director to submit additional evidence and written arguments to the Director. The Director may rely solely on the information provided by the two parties involved in the dispute, without conducting any further investigation. The Director shall provide a written finding within 60 days of the deadline for the parties' submissions. If the Director determines that the applicant has not met its obligations under Food and Agricultural Code section 12811.5(a-d), the Director shall promptly cancel the applicant's product registration.

NOTE: Authority cited: Section 12811.5, Food and Agricultural Code.

Reference: Section 12811.5, Food and Agricultural Code.